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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,894	01/30/2004	Kobi Iki	00167-0491001/PT-2634-US	4190

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

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11/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,894	Applicant(s) IKI ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20-65 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-7,13-16,25-30,36,39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,11,12,17,20-24,31-35,37,38,40,41 and 43-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/7/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received October 7, 2010, have been fully considered by the examiner. The following is a complete response to the October 7, 2010 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 8, 11, 12, 17, 20-24, 31, 33-35, 37, 38, 40, 41 and 43-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al (6,068,629) in view of the teaching of Hall et al (6,290,699).

Haissaguerre et al disclose an electrosurgical instrument comprising a shaft (28) having a flexible portion (142,144,154 - Figure 13) and a head (152) coupled to the shaft through the flexible portion. The head is pivotally coupled to the flexible portion (154) as shown in Figure 13C,"and the head includes a planar, non-conductive surface (152) having a plurality of conductive surfaces (160) mounted thereon. The electrodes may be recessed in the head as shown in Figures 6 and 13, or the electrodes may protrude from the head as shown in Figures 9 and 10. The examiner maintains that once deployed, the flexible portion is configured to passively bias the conductive surface towards tissue. The head contains a slot (Figure 13c) about which the head is configured to pivot. Haissaguerre et al show flexible portions that are enclosed by a portion of the head member (Figure 13B). The examiner maintains the connection is substantially the same as the connection shown in applicant's Figure 4,

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and that the head is inherently pivotable about the transverse axis in which the flexible portions are connected. The method of using the device to treat tissue is inherent to the structure and is fully disclosed by Haissaguerre et al. Haissaguerre et al fail to expressly show the head with the conductive surface is arranged in a relaxed state with the transverse axis being offset from the longitudinal axis of the shaft as required by independent claims 1, 33, 35, 37, 38, 40, 46, 47, 58 and 61.

Regarding the offset nature for the head member, Hall et al disclose an analogous device that comprises a shaft, a flexible portion, and a head coupled to the shaft through the flexible portion (see Figures). In particular, Hall et al teach that it is known to provide the flexible portion and the head along the axis of the shaft, as shown in Figure 1, and that it is also known to provide the flexible portion with a curve to provide the head member at an axis offset from the shaft longitudinal axis, as shown in Figures 13-15. The offset arrangement allows for treatment of tissue off-axis to the longitudinal axis.

To have provided the Haissaguerre device with bent flexible members to provide the head member with an off-axis relationship relative to the longitudinal axis of the shaft would have been an obvious design modification, particularly since Hall et al fairly teach that it is known to use either straight or bent flexible members for connecting an electrode head to an elongate shaft.

Regarding claims 2 and 4, the examiner maintains the use of Nitinol wire and springs are obvious design considerations. As addressed in the previous Office action, Haissaguerre disclose the use of Nitinol wire (col. 8, line 65) for making the flexible

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members, and the examiner maintains the use of a spring or spring material would be an obvious design alternative.

Regarding claims 8, 11 and 12, Haissaguerre clearly show and disclose the head member having a pivotal nature that meets the limitations of these claims.

Regarding claims 17, 20-24 and 31, Haissaguerre shows the various electrode configurations, including recessed (Figure 6) and extending (Figure 9) electrodes. Hall further discloses various alternative shapes for the head and electrode member. Such alternative shapes and designs are deemed to be obvious design considerations for the skilled artisan.

Regarding claims 33, 34 and 38, see rejection of claim 1 above. Haissaguerre fully disclose the method of using the device to treat tissue.

Regarding claims 35, 37, 40, 41 and 43-46 see discussion of rejections, particularly of claim 1, above.

Regarding claim 47, the Haissaguerre et al device comprises the shaft, flexible portion and head portion as addressed above. The limitation “the non-conductive surfaced sized to limit how far the electrically conductive surface can advance into tissue such that the tissue effect is limited to one or more of debriding, smoothing and sealing the tissue” is deemed to be inherently met by Haissaguerre et al. There is no disclosure of what specific dimensions are required to meet such a limitation, nor is there any recitation of the specific size. The non-conductive surface (152) would inherently prevent the conductive surfaces from advancing any further into tissue than

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the size of the non-conductive surface could allow. And the electrodes are inherently capable of providing any one of debriding, smoothing and sealing of tissue.

Regarding claims 48, 50, 52, 54, 56 and 59, the examiner maintains that the specific surface for the conductive and non-conductive surfaces would be a matter of obvious design choice for one of ordinary skill in the art. See previous Office action for discussion of this issue.

Regarding claims 51, 53, 55, 58 and 60, the examiner maintains a flexible power lead is coupled to the conductive surfaces, the lead extending through the flexible portions (142,146 – col. 13, lines 28-30).

Regarding claim 58, the examiner maintains that the head is clearly free to pivot relative to the flexible members (142,144) such that the electrode may be maintained in contact with tissue as the head moves.

Regarding newly added claims 61-65, these limitations have been effectively addressed in the discussion of the rejections above, particularly with respect to claim 1.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haissaguerre et al ('629) and Hall ('699) and further in view of the teaching of Parins et al (5,125,928).

Haissaguerre et al disclose an elongate member, but fail to specifically disclose a sheath provided for covering the flexible portion of the head for delivery of the ablation head to tissue.

Parins et al disclose another RF device that includes a shaft (62) and a pivotally mounted head (80) mounted to the shaft. Electrodes are provided on the head member for treating tissue. Further, Parins et al teach that it is known to provide a sheath member (60) which covers the flexible portion of the shaft and the head member prior to deployment to assist in delivering the device to a tissue site.

To have provided the Haissaguerre et al device, as modified by the teaching of Hall, with a sheath member to cover the head during insertion of the device to a treatment site would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Parins et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, 8, 11-12, 17, 20-24, 31-35, 37-38, 40-41, and 43-65 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of copending Application No. 10/999230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '230 application claims recite the same basic structure with only slightly modified language and obvious design alternatives.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
November 9, 2010

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